PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mark C. Shults *et al.*
Serial No.: 08/811,473 Group No.: 3301
Filed: 03/04/97 Examiner:
Entitled: **DEVICE AND METHOD FOR DETERMINING ANALYTE LEVELS**

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8(a)(1)(i)(A)

I hereby certify that this correspondence (along with any referred to as being attached or enclosed) is, on the date shown below, being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231.

Dated: September 1, 1998 By: Linda P. Collins
Linda P. Collins

Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following printed publications are referred to in the body of the specification:

- Updike *et al.*, "Laboratory Evaluation of New Reusable Blood Glucose Sensor," *Diabetes Care*, 11:801-807 (1988);
- Moatti-Sirat *et al.*, "Towards Continuous Glucose Monitoring: *In Vivo* Evaluation of a Miniaturized Glucose Sensor Implanted for Several Days in Rat Subcutaneous Tissue," *Diabetologia* 35:224-30 (1992);
- Armour *et al.*, "Application of Chronic Intravascular Blood Glucose Sensor in Dogs," *Diabetes* 39:1519-26 (1990);
- Woodward, "How Fibroblasts and Giant Cells Encapsulate Implants: Considerations in Design of Glucose Sensors," *Diabetes Care* 5:278-281 (1982);

- Bindra *et al.*, "Design and *In Vitro* Studies of a Needle-Type Glucose Sensor for Subcutaneous Monitoring," *Anal. Chem.* 63:1692-96 (1991)'
- Shults *et al.*, A Telemetry-Instrumentation System for Monitoring Multiple Subcutaneusly Impaired Glucsose Sensors," *IEEE Trans. Biomed. Eng.* 41:937-942 (1994);
- Brauker *et al.*, "Neovascularization at a Membrane-Tissue Interface Is Dependent On Microarchitecture," *Abstract from 4th World Biomaterials Congress*, Berlin (1992);
- Phillips and Smith, "Biomedical Applications of Polyurethanes: Implications of Failure Mechanisms," *J. Biomat. Appl.*, 3:202-227 (1988);
- Stokes, "Polyether Polyurethanes: Biostable or Not?," *J. Biomat. Appl.* 3:228-259 (1988);
- Updike *et al.*, Enzymatic Glucose Sensors: Improved Long-Term Performance *In Vitro* and *In Vivo*," *Am. Soc. Artificial Internal Organs* 40:157-163 (1994);
- Updike *et al.*, "Implanting the Glucose Enzyme Electrode: Problems, Progress, and Altrenative Solutions," *Diabetes Care* 5:207-21(1982);
- Rhodes *et al.*, "Prediction of Pocket-Portable and Implantable Glucose Enzyme Electrode Performance from Combined Species Permeability and Digital Simulation Analysis," *Anal. Chem.* 66:1520-1529 (1994);
- Tse and Gough, Time-Dependent Inactivation of Immobilized Glucose Oxidase and Catalase," *Biotechnol. Bioeng.* 29:705-713 (1987);
- Gilligan *et al.*, "Evaluation of a Subcutaneous Glucose Sensor Out to 3 Months in a Dog Model," *Diabetes Care* 17:882-887 (1994);
- McKean and Gough, "A Telemetry-Instrumentation System for Chronically Implanted Glucose and Oxygen Sensors," *IEEE Trans. Biomed. Eng.* 35:526-532 (1988);
- Shichiri *et al.*, :Telemetry Glucose Monitoring Device With Needle-Type Glucose Sensor: A Useful Tool for Blood Glucose Monitoring in Diabetic Individuals," *Diabetes Care* 9:298-301 (1986);
- Lyman, "Polyurethanes. I. The Solution Polymerization of Diisocyanates with Ethylene Glycol," *J. Polymer Sci.* 45:49 (1960);

- DuPont[1] Dimension AR® (Catalog); and
- DIRECT 30/30® meter (Markwell Medical) (Catalog).

The following printed publications were incorporated by reference in the body of the specification:

- U.S. Patent No. 4,757,022 to Shults *et al.*;
- U.S. Patent No. 4,994,167 to Shults *et al.*;
- U.S. Patent No. 5,380,536 to Hubbell *et al.*;
- U.S. Patent No. 5,497,772 to Schulman *et al.*;
- U.S. Patent No. 4,787,398 to Garcia *et al.*;
- U.S. Patent No. 5,321,414 to Alden and Ohno;
- U.S. Patent No. 4,823,808 to Clegg and Wallace;
- U.S. Patent No. 4,703,756 to Gough *et al.*;
- U.S. Patent No. 4,431,004 to Bessman *et al.*;
- U.S. Patent No. 4,803,243 to Fujimoto *et al.*;
- U.S. Patent No. 4,686,044 to Behnke & Pitowski;
- U.S. Patent No. 5,453,278 to Chan *et al.*;
- PCT Patent Publication No. WO 94/22367 to Fossa *et al.*;
- PCT Patent Publication No. WO 96/32076 to Neuenfeldt;
- PCT Patent Publication No. WO 96/01611 to Geller *et al.*; and
- PCT Patent Publication No. WO 92/07525 to Brauker *et al.*;

Applicants have become aware of the following printed publications which may be material to the examination of this application:

- United States Patent No. 5,469,846 to Khan.

  Khan presents a non-enzymatic implantable glucose detector. Khan is silent on the use of an angiogenic layer to promote vascularization in the sensor interface region.

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[1] Please note that Dade International purchased this product line from DuPont. A Dade catalog is therefore provided which sets out a functional overview of the Dimension AR apparatus.

- United States Patent No. 5,431,160 to Wilkins.
  Wilkins presents a reusable, enzymatic implantable glucose detector. Wilkins is silent on the use of an angiogenic layer to promote vascularization in the sensor interface region.
- United States Patent No. 5,660,163 to Schulman.
  Schulman presents an enzymatic glucose sensor assembly. Schulman is silent on the use of said sensor assembly outside of an intravenous milieu. Furthermore, Schulman is silent on the use of an angiogenic layer to promote vascularization in the sensor interface region.
- United States Patent No. 5,476,094 to Allen *et al.*
  Allen presents semi-permeable acrylic copolymer membranes suitable to interface between a sensor and a physiological milieu. Allen is silent on the use of an angiogenic layer to promote vascularization in the sensor interface region.
- United States Patent No. 4,902,294 to Gosserez.
  Gosserez presents a mammary prosthesis fabricated from a biocompatible film. Gosserez is silent on the use of an angiogenic layer to promote vascularization in a sensor interface region. Indeed, the material and design presented by Gosserez teach away from the formation of a foreign body capsule around the implanted prosthetic.
- United States Patent No. 4,353,888 to Sefton.
  Sefton presents a process for the micro-encapsulation of cells within a semipermeable polymer membrane. Sefton is silent on the use of an angiogenic layer to promote vascularization in a sensor interface region.
- PCT Patent Publication No. 92/13271 to Rhodes.
  Rhodes presents a device, implantable *in vivo*, for assaying compounds within biological fluid. Rhodes is silent on the use of a bioprotective membrane that, while not limited to any one particular mechanism or function, protects the instant biological fluid measuring device from external forces and factors that may result in environmental stress cracking.

- PCT Patent Publication No. 96/36296 to Pauley.

  Pauley presents a device, implantable *in vivo*, for holding living cells in a fully enclosed semi-permeable pocket. Pauley is silent on the use of an angiogenic layer to promote vascularization in a sensor interface region. In addition, Pauley is silent on the use of a bioprotective membrane that, while not limited to any one particular mechanism or function, protects a device for determining analyte levels from external forces and factors that may result in environmental stress cracking of a membrane comprising said analyte device.

- Fischer *et al.*, "Oxygen Tension at the Subcutaneous Implantation Site of Glucose Sensors," *Biomed. Biochim.* 11/12, 965-971 (1989).

  Fisher *et al.* presents data on oxygen tension at the implantation site of subcutaneous glucose sensors. Fisher is silent on the use of an angiogenic layer to promote vascularization in a sensor interface region.

- Brauker *et al.*, "Neovascularization of Synthetic Membranes Directed by Membrane Microarchitecture," *Journal of Biomedical Materials Research* 29:1517-1524 (1995).

  Brauker *et al.* present the use of angiogenic materials to assist in the vascularization of synthetic membrane systems enclosing cells or tissues for transplantation. Brauker *et al.* are silent on the use of such angiogenic materials in conjunction with a device for assaying biological fluids.

- Abstract presented by James Brauker, Ph.D., "Neovascularization of Cell Transplantation Devices: Membrane Architecture-Driven and Implanted Tissue-Driven Vascularization," *Baxter Healthcare Corp.*

  Brauker suggests the use of a vascularizing membrane as a tissue-contacting surface for glucose sensors. Brauker is silent on the use of a bioprotective membrane that, while not limited to any one particular mechanism or function, protects a device for determining analyte levels from external forces and factors that may result in environmental stress cracking of a membrane comprising said analyte device.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Dated: September 1, 1998

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